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Food and Drug Administration
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The Food and Drug Administration today announced the approval of tacrine hydrochloride, the first drug approved specifically to treat symptoms of Alzheimer's disease.

Alzheimer's disease, a progressive condition affecting memory, judgment and the ability to reason, affects an estimated four million Americans. Tacrine was found in two controlled trials to provide a small but clinically meaningful benefit for some patients with mild to moderate Alzheimer's disease.

"Tacrine is the first drug shown to have some effect on the disease's devastating symptoms," said FDA Commissioner David A. Kessler, M.D. "It is not a cure for Alzheimer's disease, but it provides some relief for patients and their families."

The conclusion that tacrine is effective for the treatment of symptoms of mild to moderate Alzheimer's disease was based on studies showing that the drug is superior to a placebo in influencing measurements designed to assess antidementia drugs. These measurements include a specific performance test that assesses memory and reasoning ability, and an overall assessment of function based on an interview by a trained clinician.

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An advisory panel recommended approval of tacrine in March 1993 based on new studies submitted by the manufacturer, Warner-Lambert Co. of Morris Plains, N.J., which will market the drug under the trade name Cognex. The firm conducted these studies after an advisory committee concluded in July 1991 that the available evidence based on relatively low doses did not support approval of the drug. The committee recommended that the company study use of higher doses over a longer period of time. In one of the new studies, which lasted 30 weeks, patients were given between 80 and 160 mg. of the drug.

Today's approval comes seven months after the manufacturer submitted data using the higher doses.

Because tacrine can cause mild liver toxicity, which has been reversible if tacrine treatment is withdrawn promptly, the labeling for the drug recommends an escalating dosing regimen with frequent blood tests in order to identify patients sensitive to the drug. In patients experiencing mild liver toxicity, it is often possible to continue at a lower dose or stop and then resume therapy at a lower dose. Other side effects include nausea, vomiting, diarrhea and rash.

Tacrine has been available since February 1992 to patients under a "treatment IND" protocol that has permitted more than 7,400 patients to receive the drug while the controlled clinical studies were being completed. IND stands for "investigational new drug."

FDA is one of eight Public Health Service agencies within HHS.

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